

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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STACI MONK and
JOSHUA CONNER MONK

FILED
U.S. DISTRICT COURT
★ DEC 15 2009 ★
BROOKLYN OFFICE

CV 09 - 5469 CASE NUMBER

Plaintiffs,

-against-

COMPLAINT
AND DEMAND
FOR JURY TRIAL

GLASSER, J.

BAYER CORPORATION, BAYER HEALTHCARE
PHARMACEUTICALS, INC., BAYER
HEALTHCARE LLC, BAYER HEALTHCARE AG, and
BAYER SCHERING PHARMA AG

REYES, M.J.

Defendants.
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Plaintiffs, by their attorneys, **DOUGLAS AND LONDON, P.C.**, on behalf of themselves individually, upon information and belief, at all times hereinafter mentioned, allege as follows:

JURISDICTION

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiffs reside.

NATURE OF THE CASE

2. This action is brought on behalf of Plaintiff, STACI MONK, who used the combination oral contraceptive Yasmin and/or YAZ, also known generically as drospirenone and ethinyl estradiol (hereinafter collectively referred to as "YAZ/Yasmin").

3. Defendants, BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and

BAYER SCHERING PHARMA AG (hereinafter collectively referred to as “Defendants”) designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed YAZ/Yasmin.

4. When warning of safety and risks of YAZ/Yasmin, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as “FDA”), to Plaintiff and the public in general, that YAZ/Yasmin had been tested and was found to be safe and/or effective for its indicated use.

5. Defendants concealed their knowledge of YAZ/Yasmin’s defects, from Plaintiff, the Food and Drug Administration, the public in general and/or the medical community specifically.

6. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase YAZ/Yasmin for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

7. Defendants negligently and improperly failed to perform sufficient tests, if any, on women using YAZ/Yasmin during clinical trials, forcing Plaintiff, and her physicians, hospitals, and/or the FDA, to rely on safety information that applies to other oral birth control medications, which does not entirely and/or necessarily apply to the YAZ/Yasmin whatsoever.

8. Defendants were negligent in failing to adhere to and/or take into consideration warnings from the FDA, who determined that the Defendants were misleading the public in general, and the medical community in particular, through the use of advertisements which overstated the efficacy of YAZ/Yasmin and minimized the serious risks of the drug.

9. As a result of the defective nature of YAZ/Yasmin, those persons who use and/or used and relied on YAZ/Yasmin have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, and/or sudden

death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

10. Plaintiff herein has sustained certain of the above health consequences due to her use of YAZ/Yasmin.

11. Defendants concealed their knowledge of the defects in their products from the Plaintiff, and her physicians, hospitals, pharmacists, the FDA, and the public in general.

12. Consequently, Plaintiff seeks compensatory damages as a result of her use of the YAZ/Yasmin, which has caused, may cause, and/or will continue to cause Plaintiff to suffer and/or be at greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

13. Plaintiff, STACI MONK, is a citizen of the United States of America, and is a resident of the State of Texas.

14. Plaintiff, STACI MONK, was born on July 22, 1986.

15. Plaintiff, STACI MONK, first began using YAZ/Yasmin in or about August, 2007, and used YAZ/Yasmin up through approximately October, 2007.

16. As result of using Defendants' YAZ/Yasmin, Plaintiff STACI MONK, was caused to suffer tachycardia, which required subsequent ablation procedures, in January, 2008, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

17. The injuries and damages sustained by Plaintiff, STACI MONK, were caused by Defendants' YAZ/Yasmin.

18. Plaintiff, JOSHUA CONNER MONK, is a natural person and a citizen of the United States and a resident of the State of Texas and is the lawful spouse of Plaintiff STACI MONK.

PARTY DEFENDANTS

19. Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

20. Defendant BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of SCHERING BERLIN, INC., Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

21. At relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin.

22. At relevant times, Defendant BAYER CORPORATION conducted regular and sustained business in the states of Texas and New York by selling and distributing its products in the states of Texas and New York and engaged in substantial commerce and business activity in the states of Texas and New York.

23. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

24. Upon information and belief, at all relevant times Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. has transacted and conducted business in the states of Texas and New York, and derived substantial revenue from interstate commerce.

25. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. expected or should have expected that its acts would have consequences within the United States of America, and in the states of Texas and New York, and derived substantial revenue from interstate commerce.

26. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is the holder of approved New Drug Application No. 21-676 for YAZ.

27. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

28. Upon information and belief, Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the state of New York.

29. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC has transacted and conducted business in the states of Texas and New York, and derived substantial revenue from interstate commerce.

30. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC expected or should have expected that its acts would have consequences within the United States of America, and in the states of Texas and New York, and derived substantial revenue from interstate commerce.

31. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

32. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER SCHERING PHARMA AG.

33. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG has transacted and conducted business in the States of Texas and New York and derived substantial revenue from interstate commerce.

34. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences within the United States of America, and in the states of Texas and New York, and derived substantial revenue from interstate commerce.

35. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG exercises dominion and control over Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER SCHERING PHARMA AG.

36. Upon information and belief, Defendant BAYER SCHERING PHARMA AG is a company domiciled in Germany.

37. Upon information and belief, Defendant BAYER SCHERING PHARMA AG has transacted and conducted business in the states of Texas and New York and derived substantial revenue from interstate commerce.

38. Upon information and belief, Defendant BAYER SCHERING PHARMA AG expected or should have expected that its acts would have consequences within the United State of America, and in the states of Texas and New York, and derived substantial revenue from interstate commerce.

39. Upon information and belief, and at all relevant times Defendant BAYER SCHERING PHARMA AG was in the business of and did design, research, manufacture, test, advertise, promote,

market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

FACTUAL BACKGROUND

40. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed YAZ/Yasmin for use as a combination oral contraceptive.

41. Yasmin, the predecessor to YAZ, first received FDA approval in 2001 as a combination oral contraceptive.

42. Each tablet of Yasmin is composed of a combination of 3 mg of the progestin, drospirenone, and 0.03 mg of the estrogen, ethinyl estradiol.

43. YAZ received FDA approval in 2006 as a combination oral contraceptive.

44. YAZ is almost identical to Yasmin, but each tablet of YAZ is composed of the combination of 3 mg of the progestin, drospirenone, and only 0.02 mg of the estrogen, ethinyl estradiol.

45. YAZ and Yasmin are indicated for the prevention of pregnancy in women who use an oral contraceptive.

46. Combination birth control pills are referred to as combined hormonal contraceptives.

47. The primary difference between YAZ/Yasmin and other oral contraceptives on the market is that drospirenone has never been marketed in the United States and is unlike other progestins available in the United States.

48. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

49. In February 2003, a paper entitled *Thromboembolism associated with the new contraceptive YAZ/Yasmin* was published in the British Medical Journal detailing a Netherlands

Pharmacovigilance Centre report of additional reports of thromboembolism where YAZ/Yasmin was suspected as the cause, including two deaths.

50. Upon information and belief, Adverse Event data maintained by the FDA indicate staggering, serious Adverse Events, including, heart arrhythmias, electrolyte imbalance, hyponatremia, hyperkalemia, hyperkalemic arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, stroke, transient ischemic attack, blood clots, embolisms, and/or sudden death.

51. Defendants have marketed their drug YAZ/Yasmin as effective for the treatment of premenstrual dysphoric disorder (hereinafter referred to as "PMDD"), premenstrual syndrome (hereinafter referred to as "PMS") and moderate acne, in addition to its FDA approved use as an oral contraceptive, and that it lacks certain side effects, such as weight gain, bloating and water retention, common to many other oral contraceptives.

52. Defendants have been warned at least three times by the FDA; in 2003, 2008 and 2009, for misleading the public through use of television advertisements which overstate the efficiency of YAZ and/or Yasmin and minimize serious risks associated with the drug.

53. The use of YAZ/Yasmin has a prothrombotic effect resulting in the development of thromboses, such as pulmonary emboli and deep vein thrombosis.

54. Defendants ignored the correlation between the use of YAZ/Yasmin and the increased risk of developing thromboses, despite the wealth of scientific and medical evidence available.

55. The use of drospirenone, a diuretic, in YAZ/Yasmin creates unique and dangerous risks compared to other oral contraception. These risks include, including inter alia heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including sudden death, stroke, transient ischemic attack, embolisms, blood clots, kidney and/or gallbladder disease.

56. Upon information and belief, drospirenone acts as a diuretic, where it goes into the kidney and blocks aldosterone, a hormone that increases the reabsorption of sodium and water and secretes potassium, causing dehydration.

57. Upon information and belief, the use of drospirenone in YAZ/Yasmin and the blockage of aldosterone causes an imbalance in electrolytes by reducing sodium, a condition known as hyponatremia, and increasing potassium, a condition known as hyperkalemia, which may lead to serious and potentially fatal conditions known as hyperkalemia arrhythmia, myocardial infarction, stroke, transient ischemic attacks, blood clots, embolisms, and/or sudden death.

58. Upon information and belief, hyperkalemia arrhythmias are also associated with blood clots and/or thrombotic events such as a stroke, deep vein thrombosis, pulmonary embolism or heart attack.

59. Upon information and belief, the use of drospirenone in YAZ/Yasmin is also known to cause gallbladder disease, which could require surgical intervention.

60. Upon information and belief, Drospirenone has also been known to cause kidney stone formation, which may also cause further kidney disease and require surgery.

61. The Defendants did not provide adequate warnings to doctors, the health care community and the general public about the increased risk of serious adverse events that are described herein and that have been repeated by the medical community.

62. By reason of the foregoing, Plaintiff has developed and/or is at extremely high risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

63. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has and/or may suffer serious and dangerous side effects including,

inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

64. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendants' YAZ/Yasmin drug.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

65. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

66. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of YAZ/Yasmin into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

67. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of YAZ/Yasmin into interstate commerce in that Defendants knew or should have known that using YAZ/Yasmin created a high risk of unreasonable, dangerous side effects, including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient

ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

68. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- (a) Manufacturing, producing, promoting, formulating, creating, and/or designing YAZ/Yasmin without thoroughly testing it;
- (b) Manufacturing, producing, promoting, formulating, creating, and/or designing YAZ/Yasmin without adequately testing it;
- (c) Not conducting sufficient testing programs to determine whether or not YAZ/Yasmin was safe for use; in that Defendants herein knew or should have known that YAZ/Yasmin was unsafe and unfit for use by reason of the dangers to its users;
- (d) Selling YAZ/Yasmin without making proper and sufficient tests to determine the dangers to its users;
- (e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of YAZ/Yasmin;
- (f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, YAZ/Yasmin;
- (g) Failing to test YAZ/Yasmin and/or failing to adequately, sufficiently and properly test YAZ/Yasmin.
- (h) Negligently advertising and recommending the use of YAZ/Yasmin without sufficient knowledge as to its dangerous propensities;
- (i) Negligently representing that YAZ/Yasmin was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently representing that YAZ/Yasmin had equivalent safety and efficacy as other forms of birth control/contraception;

- (k) Negligently designing YAZ/Yasmin in a manner which was dangerous to its users;
- (l) Negligently manufacturing YAZ/Yasmin in a manner which was dangerous to its users;
- (m) Negligently producing YAZ/Yasmin in a manner which was dangerous to its users;
- (n) Negligently assembling YAZ/Yasmin in a manner which was dangerous to its users;
- (o) Concealing information concerning FDA warnings from the Plaintiff in knowing that YAZ/Yasmin was unsafe, dangerous, and/or non-conforming with FDA regulations;
- (p) Improperly concealing and/or misrepresenting information from the Plaintiffs, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of YAZ/Yasmin compared to other forms of contraception.

69. Defendants under-reported, underestimated and downplayed the serious dangers of YAZ/Yasmin.

70. Defendants negligently compared the safety risk and/or dangers of YAZ/Yasmin with other forms of contraception, including but not limited to other combination oral contraceptives.

71. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of YAZ/Yasmin in that they:

- (a) Failed to use due care in designing and manufacturing YAZ/Yasmin so as to avoid the aforementioned risks to individuals when YAZ/Yasmin was used for contraceptive purposes;
- (b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of YAZ/Yasmin;
- (c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of YAZ/Yasmin;

- (d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning YAZ/Yasmin;
- (e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- (b) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of YAZ/Yasmin;
- (g) Failed to warn Plaintiff, prior to actively encouraging the sale of YAZ/Yasmin, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;
- (h) Were otherwise careless and/or negligent.

72. Despite the fact that Defendants knew or should have known that YAZ/Yasmin caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell YAZ/Yasmin to consumers, including the Plaintiff.

73. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

74. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which she suffered and/or will continue to suffer.

75. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

76. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

77. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)

78. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

79. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed YAZ/Yasmin as hereinabove described that was used by the Plaintiff.

80. That YAZ/Yasmin was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

81. At those times, YAZ/Yasmin was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

82. The combination oral contraceptive, YAZ/Yasmin, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of YAZ/Yasmin.

83. The combination oral contraceptive, YAZ/Yasmin, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

84. At all times herein mentioned, YAZ/Yasmin was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

85. Defendants knew, or should have known that at all times herein mentioned its YAZ/Yasmin was in a defective condition, and was and is inherently dangerous and unsafe.

86. At the time of the Plaintiff's use of YAZ/Yasmin, YAZ/Yasmin was being used for the purposes and in a manner normally intended, namely for birth control and/or regulation of menses.

87. Defendants with this knowledge voluntarily designed its YAZ/Yasmin in a dangerous condition for use by the public, and in particular the Plaintiff.

88. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

89. Defendants created a product unreasonably dangerous for its normal, intended use.

90. The combination oral contraceptive, YAZ/Yasmin, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that YAZ/Yasmin left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

91. The combination oral contraceptive, YAZ/Yasmin, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' YAZ/Yasmin was manufactured.

92. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

93. The Plaintiff could not by the exercise of reasonable care, have discovered YAZ/Yasmin's defects herein mentioned and perceived its danger.

94. The combination oral contraceptive, YAZ/Yasmin, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

95. The combination oral contraceptive, YAZ/Yasmin, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

96. The combination oral contraceptive, YAZ/Yasmin, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and permanent health consequences from YAZ/Yasmin, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, YAZ/Yasmin.

97. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, YAZ/Yasmin.

98. Defendants' defective design, manufacturing defect, and inadequate warnings of YAZ/Yasmin were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

99. That said defects in Defendants' drug YAZ/Yasmin were a substantial factor in causing Plaintiff's injuries.

100. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences .

101. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

102. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

103. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

104. Defendants expressly warranted that YAZ/Yasmin was safe and well accepted by users.

105. The combination oral contraceptive YAZ/Yasmin does not conform to these express representations because YAZ/Yasmin is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

106. Plaintiffs did rely on the express warranties of the Defendants herein.

107. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of YAZ/Yasmin in recommending, prescribing, and/or dispensing YAZ/Yasmin.

108. The Defendants herein breached the aforesaid express warranties, as their drug YAZ/Yasmin was defective.

109. Defendants expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that YAZ/Yasmin was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of combination oral contraceptives, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

110. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that YAZ/Yasmin was not safe and fit for the use intended, and, in

fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

111. As a result of the foregoing acts and/or omissions the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

112. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendants' YAZ/Yasmin drug.

113. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

114. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

115. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

116. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold YAZ/Yasmin and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold YAZ/Yasmin, for use in contraception.

117. At the time Defendants marketed, sold, and distributed YAZ/Yasmin for use by Plaintiff, Defendants knew of the use for which YAZ/Yasmin was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

118. The Defendants impliedly represented and warranted to the users of YAZ/Yasmin and their physicians, healthcare providers, and/or the FDA that YAZ/Yasmin was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

119. That said representations and warranties aforementioned were false, misleading, and inaccurate in that YAZ/Yasmin was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

120. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

121. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether YAZ/Yasmin was of merchantable quality and safe and fit for its intended use.

122. The combination oral contraceptive YAZ/Yasmin was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

123. The Defendants herein breached the aforesaid implied warranties, as their drug YAZ/Yasmin was not fit for its intended purposes and uses.

124. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

125. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

126. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**FIFTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
(FRAUDULENT MISREPRESENTATION)**

127. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

128. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiffs, and/or the FDA, and the public in general, that said product, YAZ/Yasmin, had been tested and was found to be safe and/or effective for contraceptive purposes.

129. That representations made by Defendants were, in fact, false.

130. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

131. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, YAZ/Yasmin, for use as a means of birth control, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

132. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used YAZ/Yasmin, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

133. In reliance upon said representations, the Plaintiff was induced to and did use YAZ/Yasmin, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

134. Said Defendants knew and were aware or should have been aware that YAZ/Yasmin had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

135. Defendants knew or should have known that YAZ/Yasmin had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

136. Defendants brought YAZ/Yasmin to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

137. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient

ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

138. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

139. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**SIXTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
(FRAUDULENT CONCEALMENT)**

140. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

141. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of YAZ/Yasmin for its intended use.

142. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the levels of estrogen delivered by YAZ/Yasmin.

143. Defendants knew or were reckless in not knowing that its representations were false.

144. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

- (a) that YAZ/Yasmin was not as safe as other forms of contraception;
- (b) that the risks of adverse events with YAZ/Yasmin were higher than those with other forms of birth control, including but not limited to other forms of oral contraception;
- (c) that the risks of adverse events with YAZ/Yasmin were not adequately tested and/or known by Defendants;
- (d) that Defendants were aware of dangers in YAZ/Yasmin, in addition to and above and beyond those associated with other forms of oral birth control methods;
- (e) that YAZ/Yasmin was defective, and that it caused dangerous side effects, including but not limited to higher incidence of stroke, transient ischemic attack ("TIA"), embolisms, blood clots, heart attacks, coma, and death, as well as other severe and permanent health consequences, in a much more and significant rate than other forms of birth control, including but not limited to oral birth control;
- (f) that patients needed to be monitored more regularly than normal while using YAZ/Yasmin;
- (g) that YAZ/Yasmin was manufactured negligently;
- (h) that YAZ/Yasmin was manufactured defectively;
- (i) that YAZ/Yasmin was manufactured improperly;
- (j) that YAZ/Yasmin was designed negligently;
- (k) that YAZ/Yasmin was designed defectively; and
- (l) that YAZ/Yasmin was designed improperly.

145. Defendants were under a duty to disclose to Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of YAZ/Yasmin, including but not limited to the heightened risks of an adverse cardiovascular event, such as a heart arrhythmia, myocardial infarction or sudden death.

146. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used YAZ/Yasmin, including the Plaintiffs, in particulars.

147. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of YAZ/Yasmin was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and her physicians, hospitals and healthcare providers into reliance, continued use of YAZ/Yasmin, and actions thereon, and to cause them to purchase, prescribe, and/or dispense YAZ/Yasmin and/or use the product.

148. Defendants knew that Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding YAZ/Yasmin, as set forth herein.

149. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

150. As a result of the foregoing acts and omissions the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

151. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

152. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**SEVENTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
(NEGLIGENT MISREPRESENTATION)**

153. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

154. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, YAZ/Yasmin, had been tested and found to be safe and effective for birth control.

155. The representations made by Defendants were, in fact, false.

156. Defendants failed to exercise ordinary care in the representation of YAZ/Yasmin, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendants negligently misrepresented YAZ/Yasmin's high risk of unreasonable, dangerous side effects.

157. Defendants breached their duty in representing YAZ/Yasmin's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

158. As a result of the negligent misrepresentations of the Defendants set forth hereinabove, said Defendants knew and were aware or should have known that YAZ/Yasmin had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature.

159. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

160. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

EIGHTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
(FRAUD AND DECEIT)

161. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

162. Defendants conducted research and used YAZ/Yasmin as part of their research.

163. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that YAZ/Yasmin was safe and effective for use as a means of providing birth control.

164. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

165. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiffs, as well as their respective healthcare providers and/or the FDA.

166. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print

ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

167. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug YAZ/Yasmin was safe and effective for use as a form of birth control.

168. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug YAZ/Yasmin carried the same risks, hazards, and/or dangers as other forms of combination oral birth contraception.

169. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug YAZ/Yasmin was more effective in treating the symptoms of premenstrual dysphoric disorder and moderate acne than other forms of combination oral contraceptives, encouraging the use of YAZ/Yasmin in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risk associated with YAZ/Yasmin.

170. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that YAZ/Yasmin was not injurious to the health and/or safety of its intended users.

171. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that YAZ/Yasmin was as potentially injurious to the health and/or safety of its intended as other forms of oral forms combination oral contraceptives.

172. These representations were all false and misleading.

173. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that YAZ/Yasmin was not safe as a means of contraception and/or was not as safe as other means of contraction, including but not limited to other forms of combination oral contraceptives.

174. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of YAZ/Yasmin, specifically but not limited to YAZ/Yasmin not having dangerous and serious health and/or safety concerns.

175. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of YAZ/Yasmin, specifically but not limited to YAZ/Yasmin being as safe a means of birth control as other forms of combination oral contraception.

176. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of YAZ/Yasmin and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use YAZ/Yasmin.

177. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that YAZ/Yasmin was fit and safe for use as birth control.

178. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that YAZ/Yasmin was fit and safe for use as birth control and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of combination oral contraceptives.

179. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that YAZ/Yasmin did not present serious health and/or safety risks.

180. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that YAZ/Yasmin did not present health and/or safety risks greater than other oral forms of contraception.

181. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

182. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiffs, including their respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe YAZ/Yasmin.

183. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of YAZ/Yasmin to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of oral contraception.

184. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of YAZ/Yasmin by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of YAZ/Yasmin.

185. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on YAZ/Yasmin and/or that their respective healthcare providers would dispense, prescribe, and/or recommend the same.

186. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

187. Defendants utilized direct-to-consumer advertizing to market, promote, and/or advertise YAZ/Yasmin.

188. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of birth control and were thereby induced to purchase, use and rely on Defendants' drug YAZ/Yasmin.

189. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of YAZ/Yasmin.

190. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

191. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of YAZ/Yasmin, Plaintiff would not have purchased, used and/or relied on Defendants' drug YAZ/Yasmin.

192. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

193. As a result of the foregoing acts and omissions Plaintiff was caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as

well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

194. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

195. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**NINTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
(LOSS OF CONSORTIUM ON BEHALF OF
PLAINTIFF JOSHUA CONNER MONK)**

196. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

197. Plaintiff, JOSHUA CONNER MONK was and is the lawful spouse of Plaintiff STACI MONK, and as such, was and is entitled to the comfort, enjoyment, society and services of his spouse.

198. As a direct and proximate result of the foregoing, Plaintiff JOSHUA CONNER MONK was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff STACI MONK, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. The Plaintiffs, STACI MONK and JOSHUA CONNER MONK'S injuries and damages are permanent and will continue into the future. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

199. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;
2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;
3. Awarding Plaintiffs reasonable attorneys' fees;
4. Awarding Plaintiffs the costs of these proceedings; and
5. Such other and further relief as this Court deems just and proper.

Dated: New York, New York
December 15, 2009

DOUGLAS & LONDON, P.C.

By: 

MICHAEL A. LONDON (ME-7510)

111 John Street, Suite 1400

New York, New York 10038

Ph: (212) 566-7500

Fax: (212) 566-7501

Email: mlondon@douglasandlondon.com

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.



MICHAEL A. LONDON (ML-7510)